

Message Text

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ORIGIN HEW-06

INFO OCT-01 EUR-12 EA-09 NEA-10 ISO-00 OES-06 MED-03 EB-07

COME-00 /054 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

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DHEW/OIH: MACODDING(INFO)

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FM SECSTATE WASHDC

TO AMEMBASSY CANBERRA PRIORITY

AMEMBASSY BRUSSELS PRIORITY

AMEMBASSY TEHRAN PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY LONDON PRIORITY

UNCLAS STATE 216048

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, AS, BE, IR, SP, SW, UK

SUBJECT: DEFECTIVE PERITONEAL DIALYSIS FILTER SET (RE-
CALL T-143-6)

1. FDA ADVISES OF THE FOLLOWING DEVICE RECALL:

PRODUCT INVOLVED: PRESCRIPTION DEVICE USED FOR PERITONEAL
DIALYSIS OF PATIENTS WITH DEFICIENT OR NON-FUNCTIONING
KIDNEYS. THE FILTER SET CONSISTS OF A 90 MM BLUE PLASTIC
DISK CONTAINING A 0.22 MICRON MILLIPORE FILTER WHICH HAS
AN INLET AND OUTLET SPOUT WITH APPROXIMATELY 4 FEET OF
CLEAR PLASTIC PVC TUBING RUNNING FROM EACH SPOUT. DEVICE
IS LABELED STERILE AND NON-PYROGENIC. IT IS EQUIPED WITH
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EITHER UNVENTED (REFERRED TO AS BAXTER) OR VENTED (REF-

ERRED TO AS CUTTER) FITTINGS ON THE TUBING. CURRENTLY, THE SET IS PACKAGED IN INDIVIDUAL HEAT SEALED ENVELOPE WITH CLEAR SIDE AND WHITE TYVAC SIDE. PRIOR TO LATE 1975 SET WAS PACKAGED IN A BLISTER PACK. UNITS ARE SOLD IN TWO UNIT AND TEN UNIT MASTER CARTONS.

PRODUCT IDENTIFICATION: THE FILTER SET IN THE ENVELOPE PACK IS LABELED "MILLIPORE PERIDEX PERITONEAL DIALYSIS 0.22 MICRON FILTER SET, MILLIPORE CORPORATION, BEDFORD, MASSACHUSETTS 01730, STERILE, NON-PYROGENIC".

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THE FILTER SET IN THE BLISTER PACK USED PRIOR TO LATE 1975 IS LABELED "THE MILLIPORE PERITONEAL DIALYSIS ADMINISTRATION SET WITH FILTER, MILLIPORE CORPORATION, BEDFORD, MASSACHUSETTS 01730".

LOTS AND CATALOGUE NUMBERS INVOLVED: ALL LOTS ARE UNDER RECALL. THE FOUR CATALOGUE NUMBERS ARE AS FOLLOWS:

PMGS090D1, BAXTER (UNVENTED) FITTING, 10 PACK
PMGS090D2, BAXTER (UNVENTED) FITTING, 2 PACK
PMGS090D3, CUTTER, (VENTED) FITTING, 10 PACK
PMGS090D4, CUTTER (VENTED) FITTING, 2 PACK

MANUFACTURER/RECALLING FIRM:

MILLIPORE CORPORATION
ASHBY ROAD
BEDFORD, MASS. 01730

2. REASON FOR RECALL: FOLLOWING A COMPLAINT THAT A FILTER SET LEAKED FROM HAIR LINE CRACKS IN THE PLASTIC ON THE EXIT SPOUT OF THE FILTER SET AND THAT THE TUBING WAS KINKED THE FIRM WAS INSPECTED BY FDA ON 7/30/76. INSPECTION REVEALED THAT VISUAL AND FUNCTIONAL DEFECTS (CRACKS) IN A LARGE PERCENTAGE OF FILTER SETS WERE FOUND IN THE INLET, BODY AND EXIT SPOUT OF THE RIGID PLASTIC HOUSING FOR THE FILTER. OF THESE VISUAL DEFECTS, APP-
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ROXIMATELY ONE IN THREE WERE FOUND TO BE FUNCTIONAL (PRODUCING LEAKAGE). LEAKAGE IN THE EXIT SPOUT, WHICH IS IN THE STERILE REGION OF THE UNIT COULD LEAD TO THE POSSIBLE CONTAMINATION OF THE FILTERED DIALYSATE. ON 8/3/76 THE FIRM SENT RECALL LETTERS AND TELEGRAMS TO CONSIGNEES ALERTING THEM TO THE RECALL SITUATION. THE FIRM CURRENTLY BELIEVES THAT THE CRACKING OF THE PLASTIC HOUSING OF THE FILTER IS DUE TO A CHEMICAL REACTION OF

THE PVC PLASTIC IN THE TUBING AND THE PLASTIC FILTER HOUSING WHICH OCCURS DURING ETO STERILIZATION AND WHICH PRODUCES STRUCTURAL WEAKENING OF PLASTIC WHICH IS APPARENT ONLY SOMETIME AFTER STERILIZATION.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL INFORMATION DATED 8/3/76. ANY QUESTIONS CONSIGNEES MAY HAVE WITH REGARD TO THIS RECALL SHOULD BE DIRECTED TO THE FIRM.

4. FOREIGN CONSIGNEES AS FOLLOWS:

MILLIPORE PTY. LTD.
P O BOX 303, NORTH RYDE NSW2113
AUSTRALIA

MILLIPORE BENELUX
10 HELIOTROPES AVENUE
1030 BRUSSELS
ZAVNTM, BELGIUM

SOOFER CO.,
TEHERAN, IRAN

MILLIPORE IBERICA S.A.
EXPLANADA 5,
MADRID 3, SPAIN

MILLIPORE A B
BOX 17094, RIDDAREGATAN 15
GOTHENBURG, SWEDEN

MILLIPORE UK UNLIMITED
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MILLIPORE HOUSE, ABBEY ROAD
LONDON, ENGLAND ROBINSON

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NNN

Message Attributes

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Margaret P. Grafeld
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To: CANBERRA
BRUSSELS
MULTIPLE
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